

REMARKS

Claims 50-100 are currently pending in the present application. Applicants have not amended the claims with this response and therefore have not provided a listing of the claims in accordance with 37 C.F.R § 1.121 (c).

Applicants have reviewed the Examiner's response on page 4 of the Office Action mailed May 13, 2008. Applicants respectfully assert that the Examiner has erroneously characterized the features of Applicants' claims.

Applicants respectfully request reconsideration.

I. **Miskinyar (U.S. 5,527,287)**

With respect to Miskinyar, the Examiner has erroneously limited the Applicants' arguments and the "features upon which applicant relies" to be "that the insertion set is separable **while the cannula is disposed within the patient**" (emphasis in the Office Action). Applicants have not recited this limitation in the independent claims 72, 90, 93, 97 and 100 that have been rejected as being anticipated by Miskinyar. Applicants have provided arguments discussing the separability of the insertion set from the device housing or portions thereof to distinguish Miskinyar. (See Response dated April 15, 2008.) Miskinyar is another example of an inoculator where nothing is configured to be removably mounted in the device housing, much less a separable medical device or component. Miskinyar clearly does not anticipate Applicants' claims 72, 78, 80-88 and 90-100 as previously discussed thoroughly in the Response dated April 15, 2008.

Therefore, Applicants respectfully request that the rejection of claims 72, 78, 80-88 and 90-100 under 35 U.S.C. 102(b) be withdrawn.

II. **Safabash (6,293,925)**

With respect to Safabash, the Examiner's brief statement does not even address Applicants' claim limitations such as the limitation in claim 72, requiring "a removable cover member covering an opening defined in said forward end and connected to a portion of said device housing; said cover member and said device housing assuring sterile conditions of said separable insertion set within said device housing prior to removal of said cover member." As stated in the Response dated April 15, 2008, Applicants' independent claims 72, 90, 93 and 97 each require a cover connected to a portion of a

device **housing**. Further as discussed in the April 15, 2008 Response, claims 50, 72, 90 and 97 also require a sterile insertion set where the cover assures sterility of the insertion set prior to removal of the cover. Safabash discloses several embodiments of an injector having an open housing end portion. None of the embodiments of Safabash show a cover connected to the housing. Safabash also does not teach or suggest a cover for ensuring sterility of a medical device or an infusion set. Safabash does not even contemplate providing to the patient an injector with a medical device already contained therein and having a cover for ensuring sterility of the infusion set therein. These claim limitations and arguments have been thoroughly discussed in the April 15, 2008 Response.

Applicants respectfully request that the rejection of claims 50-57, 59, 65-68, 72, 78-85, 89 and 93-99 under 35 U.S.C. 102(e) be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 103

Applicants respectfully request reconsideration of the rejections of the additional pending claims as being obvious in view of Miskinyar or Safabash in combination with an additional reference based on the discussion of Miskinyar and Safabash above. These references have been discussed in detail in the Response dated April 15, 2008.

Applicants respectfully request that the rejection of claim 58 under 35 U.S.C. 103(a) as being unpatentable over Safabash and further in view of Teeple, Jr. be withdrawn.

Applicants further respectfully request that the rejection of claims 69-71, 86-88, 90-92 and 100 under 35 U.S.C. § 103(a) as being unpatentable over Safabash and further in view of Miskinyar be withdrawn.

IV. Allowable Subject Matter

Applicants kindly thank the Examiner for indicating that claims 60-64 are allowed. Applicants also kindly thank the Examiner for indicating that claims 73-77 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim.

Application Serial No. 10/813,214
Reply to Office Action mailed May 13, 2008
Response dated July 14, 2008

V. SUMMARY

It is respectfully asserted that the claims properly define the invention and that the invention is both novel and non-obvious. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

July 14, 2008

Date



Heidi A. Dare (Reg. No. 50,775)

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4809